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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/622,538

07/21/2003

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81190-2202

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03/25/2008

EXAMINER

VU, JAKE MINH

ART UNIT

PAPER NUMBER

1618

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

|                              |                                      |                                      |  |
|------------------------------|--------------------------------------|--------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/622,538 | <b>Applicant(s)</b><br>PIERCE ET AL. |  |
|                              | <b>Examiner</b><br>JAKE M. VU        | <b>Art Unit</b><br>1618              |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 December 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9, 11, 12 and 15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9, 11, 12 and 15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### DETAILED ACTION

Receipt is acknowledged of Applicant's Amendment and Request for continued Examination filed on 12/11/2007.

- Claims 9 and 12 have been amended.
- Claim 13 has been cancelled.
- Claim 15 has been added.
- Claims 9, 11, 12 and 15 are pending in the instant application.

### ***Claim Rejections - 35 USC § 102***

Claims 9, 11, and 12 rejected under 35 U.S.C. 102(b) as being anticipated by WEISS et al (US 4,918,104) in light of KODALI (US 6,303,803) and SILVA (Cholesterol: A marker for the presence of animal material in feed: January 17, 2003. [http://www.aafco.org/FDA\\_AAFCO\\_BSE\\_Workshop\\_Jan\\_2003/tabid/81/Default.aspx](http://www.aafco.org/FDA_AAFCO_BSE_Workshop_Jan_2003/tabid/81/Default.aspx)) **are maintained** for reasons of record in the previous office action filed on 07/11/2007.

Applicant argues that WEISS does not disclose flaxseed. The Examiner finds this argument unpersuasive, because WEISS disclosed using linseed oil (see col. 2, line 66-8), which is flaxseed oil.

Applicant argues that the 18:3 omega-3 fatty acid is linolenic acid and the values obtained by WEISS are lower than those obtained by Applicant, that is, not greater than 20%. The Examiner finds this argument unpersuasive, because it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben*

*Venue Laboratories*, 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same animal is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Thus, WEISS teaches, either expressly or impliedly, each and every limitation of the instant claims, including "wherein the concentration of 18:3 omega-fatty acid in said animal is greater than 20% of all fatty acids as a result of administration of said supplemented feed to said animal".

Claims 9, 11, and 12 rejected under 35 U.S.C. 102(b) as being anticipated by GARG et al (Effect of dietary cholesterol and/or omega 3 fatty acids on lipid composition and delta 5-desaturase activity of rat liver microsomes. J Nutr. 1988 Jun;118(6):661-8) **are maintained** for reasons of record in the previous office action filed on 07/11/2007. Applicant argues that GARG does not teach or suggest that administering to an animal feed supplemented with 0.1-5% cholesterol and 0.1-25% flaxseed would result in the

Art Unit: 1618

concentration of 18:3 omega-3 fatty acid in said animal being greater than 20% of all fatty acids as a result of administration of said supplemented feed to said animal. The Examiner finds this argument unpersuasive, because it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories*, 58 USPQ2d 1508 (CAFC 2001). "It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable." *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same animal is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method.

Thus, GARG teaches, either expressly or impliedly, each and every limitation of the instant claims, including "wherein the concentration of 18:3 omega-fatty acid in said animal is greater than 20% of all fatty acids as a result of administration of said supplemented feed to said animal". Additionally, GARG does show that 18:3 omega-3 fatty acid increase with a diet of linseed oil and cholesterol in the liver (see pg. 666, Table 5).

Claim 9 rejected under 35 U.S.C. 102(b) as being anticipated by FERRIER et al (alpha-Linolenic acid- and docosahexaenoic acid-enriched eggs from hens fed flaxseed: influence on blood lipids and platelet phospholipid fatty acids in humans. Am J Clin Nutr. 1995 Jul;62(1):81-6) in light of KODALI (US 6,303,803) **is withdrawn** in view of Applicant's Amendment.

However, upon further consideration, a new ground(s) of rejection is made as discussed below.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9, 11, 12 and 15 are rejected under 35 U.S.C. 102(b) as being anticipated by PRASAD (US 5,846,944) in view of KOFSKY et al (US 3,862,336).

Applicant's claims are directed to a method of increasing uptake of omega-3 fatty acids in an animal comprising administering a composition comprising of: 0.1-5% cholesterol and 0.1-25% flaxseed, wherein the composition is in the form of a pellet.

PRASAD teaches a method of administering to animals, such as rabbits, a composition comprised of: 1% cholesterol and 15% flaxseed (see col. 3, Table 1), wherein the composition can be in the form of a tablet (see col. 2, line 51), which would read on pellet.

Although the reference is silent about “increasing uptake of omega-3 fatty acids in an animal” and “wherein concentration of 18:3 omega-3 fatty acid in said animal is greater than 20% of all fatty acids as a result of administering of said supplemented feed to said animal”, it does not appear that the claim language or limitations result in a manipulative difference in the method steps when compared to the prior art disclosure. See *Bristol-Myers Squibb Company v. Ben Venue Laboratories*, 58 USPQ2d 1508 (CAFC 2001). “It is a general rule that merely discovering and claiming a new benefit of an old process cannot render the process again patentable.” *In re Woodruff*, 16 USPQ2d 1934, 1936 (Fed. Cir. 1990). Granting a patent on the discovery of an unknown but inherent function would remove from the public that which is in the public domain by virtue of its inclusion in, or obviousness from, the prior art. *In re Baxter Travenol Labs*, 21 USPQ2d 1281 (Fed. Cir. 1991). See M.P.E.P. 2145. On this record, it is reasonable to conclude that the same animal is being administered the same active agent by the same mode of administration in the same amount in both the instant claims and the prior art reference. The fact that Applicant may have discovered yet another beneficial effect from the method set forth in the prior art does not mean that they are entitled to receive a patent on that method. Thus, PRASAD teaches, either expressly or impliedly, each and every limitation of the instant claims.

Note, all animals produce milk and egg.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 9, 11, 12 and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over GARG (cited supra).

As discussed in above and in the previous office action, GARG disclosed a method of increasing uptake of omega-3 fatty acids (see pg. 666, left column) in a rat comprised of: administering to an animal, such as a rat, a composition comprised of: 0.12% or 0.2% (w/w) of cholesterol (see pg. 662, right column) and 16% of omega-fatty acid from a source such as linseed oil (see pg. 663, Table 1).

GARG does not teach the composition is in the form of a pellet.

KOFSKY disclosed feeding rat with food pellets were well known in the prior art (see col. 7, line 42-44).

It would have been obvious to the person of ordinary skill in the art at the time the invention was made to incorporate GARG's composition into a pellet. The person of ordinary skill in the art would have been motivated to make those modifications, because it would have been easier and less messy to feed rats with food pellets, and reasonably would have expected success because the rat food pellets were known in the art.



***Telephonic Inquiries***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JAKE M. VU whose telephone number is (571)272-8148. The examiner can normally be reached on Mon-Tue and Thu-Fri 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jake M. Vu/

Jake M. Vu, PharmD, JD  
Art Unit 1618